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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,687	02/02/2001	Noel K. Maclaren	BII-001CP	3472

959 7590 02/24/2004

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,687	MACLAREN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,16-18,20,33,34 and 36-44* is/are pending in the application.

4a) Of the above claim(s) *36-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,16-18,20,33,34 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 13, 16-18, 20, 33, 34, and 36-44 are pending in the application. Of these claims, claims 13, 16-18, 20, 33, and 42-44 are under consideration and were rejected in the prior action, mailed on June 3, 2003. Claims 36-41 were withdrawn as to non-elected inventions. In the Response filed on December 3, 2003, the Applicant cancelled claims 5, 14, 15, and 35, and amended claims 13, 16, 18, 20, 33, 34, 36, 37, and 41.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **(Prior Rejection- Maintained)** Claims 13-18, 20, 33-35, and 42-44 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using some enhancing agents to ameliorate or treat some autoimmune diseases, does not reasonably provide enablement for methods of using any bacterial enhancing agents to prevent any autoimmune disease. The claims have been amended such that claims 13, 16-18, 20, 33, 34, and 42-44 are the only claims still pending and under consideration. The claims were rejected because, it appears from the art that a particular immune cell response is required (i.e. a Th2 pathway response), and the Applicant has not demonstrated that any bacterial lysate would be capable of treating an immune response against a self antigen.

In the Response of December 3, 2003, the Applicant traversed the rejection on the grounds that the present application teaches that a Th2 immune response bias is not required, and that because such a bias is not required the Applicant has enabled those in the art to use the claimed methods without undue experimentation. These arguments are not found persuasive.

With respect to the bias towards a Th2 response, the Applicant argues that the current application teaches that no such bias is required. They first argue that "Applicants claims do not require that the claimed methods direct activation towards the Th2 pathway," and conclude from this that they should therefore "not be required to demonstrate that such direction towards the Th2 pathway occurs." This argument is not found persuasive because the enablement rejection is based on the failure of the application and the claims to make such a requirement. Because the art indicates that Th2 bias is required to treat such disorders, and because the Applicant has not established otherwise, it becomes necessary for the Applicant establish either that a Th2 bias would result from any bacterial lysate.

The Applicant continues their argument challenging the Examiner's conclusion that the Th2 response is necessary, and argues that any T cell response is sufficient. They support the argument by referring to the teachings of Kukreja et al. (J Clin Invest 109: 131-40), which teaches that the Th1 bias may not be the source of autoimmune disorders. The reference teaches that multiple immunoregulatory T cell defects underlie the development of diabetes. However, the reference also teaches, on page 138, that while methods of stimulating NK T cells "should be actively sought to provide novel therapies for the future," the reference also cautions that use of a compound for its T cell stimulatory activities could lead to "an inadvertent deviation towards a Th1 response through use of this agent ... could conceivably worsen rather than help the

underlying pathogenic process." The reference further teaches that "the respective contributions of Th1 and Th2 cytokines to the pathogenesis remain controversial." Page 131. Thus, the reference suggests that the Applicant may be correct that Th2 bias is not necessary. Nonetheless, the reference fails to teach that the induction of any T cell response would necessarily be beneficial in the treatment of autoimmune diabetes. By cautioning against the inadvertent induction of a Th1 response bias, the reference further indicates that the notion in the prior art indicating that Th1 bias is harmful has not been discounted. Furthermore, by indicating that, even after the filing date of the present application the relative effects of Th1 and Th2 activities is controversial, the art further demonstrates the complexity and unpredictability in the art regarding the treatment of the autoimmune diseases. For these reasons, the Applicant's first argument in traversal has not been found persuasive.

Thus, while the Applicant may have established that the use of certain bacterial antigens may be effective in the treatment or inhibition of immune responses against self antigens, and while the art has indicated that bacterial lysates may be effective immune response enhances, the Applicant has not established the any bacterial lysate would be effective in inducing a immune response that would be beneficial for those at risk of developing, or those suffering from, such autoimmune responses. The rejection is therefore maintained.

4. **(Prior Rejection- Withdrawn)** Claims 13-15, 17-20, 33-35, and 42-45 are rejected under 35 U.S.C. 112, first paragraph, while being enabling for methods of delaying or inhibiting the onset of immune responses to a self antigen using certain bacterial lysates, does not reasonably provide enablement for methods of preventing the development of such disorders.

The Applicant has amended the claims to read either on methods of treating patients at risk of developing, or suffering from an ongoing, immune response to a self antigen. Because the claims no longer read on methods of preventing immune responses to self-antigens, this rejection is withdrawn.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **(Prior Rejection-Withdrawn)** Claims 13, 15, 17, 18, 34, 35, 42, and 44 were rejected in the prior action under 35 U.S.C. 102(b) as being anticipated by Czinn et al., U.S. Patent 5,538,729. Claim 13 has been amended to incorporate the limitations of claim 14, which was not rejected over Czinn for the reasons indicated by the Applicant in the traversal presented in the Response. In view of this amendment, and the arguments presented in the Response, this rejection withdrawn from the claims.

7. **(Prior Rejection-Withdrawn)** Claims 13, 15, 17, 18, 33, 34, 35, 42, and 44 were rejected in the prior action under 35 U.S.C. 102(b) as being anticipated by Monti, EP 0269928.

This rejection is withdrawn for the reasons indicated with reference to the Czinn reference above.

8. **(Prior Rejection-Withdrawn)** Claims 13, 15, 17, 34, 35, 42, and 44 were rejected under 35 U.S.C. 102(e) as being anticipated by Fattom et al., U.S. Patent 6,294,177. This rejection is withdrawn for the reasons indicated with reference to the Czinn reference above.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. **(Prior Rejection- Withdrawn)** Claims 13-15, 17, 18, 33, 34, 35, 42, and 44 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over the teachings of Salk et al., U.S. 6,017,543. This rejection is withdrawn in view of both the amendment of the claims, and the arguments presented in traversal of the rejection in the Response.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner

JAMES HOUSEL 2/23/04
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